



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20281
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,771	05/03/2001	Toshiaki Ito	033808/0278757	6625

7590

08/16/2002

Pillsbury Winthrop LLP
50 Fremont Street
San Francisco, CA 94105

EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/16/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,771

Applicant(s)

ITO ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Restrictions

1. Applicant's election without traverse of Group I, claims 1-3, filed 12 June 2002 in Paper No. 6 is acknowledged. However, upon further consideration of the prior art, the restriction requirement is withdrawn.

Claims 1-4 are under prosecution.

Specification

2. The abstract of the disclosure is objected to because the abstract contains two separate paragraphs and contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1634

Claim 4 is indefinite for the recitation "injecting the biochip-producing solution from the inkjet device" because it is unclear whether the solution is injected into the device or ejected from the device. It is suggested that the claim be amended to clarify as described in the specification e.g. replace "injecting" with "ejecting".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirota et al (U.S. Patent No. 6,365,378 B1, filed 23 October 2000).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Regarding Claim 1, Hirota et al disclose a biochip producing solution comprising a first solution containing a biopolymer (DNA) and a second solution having a different specific gravity from that of the first solution so that the second solution is not mixed with the first solution i.e. the sample solution comprises solutions of different specific gravity and the specific gravity is analyzed during biochip production to determine the presence of biopolymers (Column 11, lines 20-40).

Regarding Claim 2, Hirota et al disclose a biochip producing solution comprising a first solution containing a biopolymer (DNA) and a second solution having a different specific gravity from that of the first solution so that the second solution is not mixed with the first solution i.e. the sample solution comprises solutions of different specific gravity and the specific gravity is analyzed during biochip production to determine the presence of biopolymers (Column 11, lines 20-40) because the solution comprises solutions of different specific gravity, the specific gravity of one of the solutions is lower than the other. Therefore, Hirota et al disclose the biochip solution as claimed.

Regarding Claim 4, Hirota et al disclose a method for producing a biochip comprising putting a biochip-producing solution containing a biopolymer into an inkjet device; and injected the biochip-producing solution from the inkjet device to a substrate to immobilize a spot of the biopolymer on the substrate wherein the solution is the solution of Claim 1 or Claim 2 (Column 4, lines 8-30 and Claims 2 and 10).

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Perkin Elmer Cetus (GeneAmp™ DNA Amplification Reagent Kit, 1988).

The claims are drawn to a biochip-producing solution comprising a first solution containing a biopolymer and a second solution having a different specific gravity from that of the first solution.

The courts have stated that a preamble is generally not accorded any patentable weight where it merely recites the intended use, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone (see *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 481). In the instant case, the preamble "biochip-producing solution" is not accorded any patentable weight because it merely recites the intended use for the solution and because the components of the solution (i.e. a first solution containing a biopolymer and a second solution having a different specific gravity from that of the first solution), are able to stand alone and are capable of performing the intended use.

Regarding Claim 1, Perkin Elmer Cetus disclose solution (PCR Reaction Mix) comprising a first solution containing a biopolymer (primer) and a second solution (oil layer) having a different specific gravity from that of the first solution so that the second solution is not mixed with the first solution i.e. the PCR reaction mix is overlayed with oil (see page 2 of the instructions, ¶ 2.)

Regarding Claim 2, Perkin Elmer Cetus disclose solution (PCR Reaction Mix) comprising a first solution containing a biopolymer (primer) and a second solution (oil layer) having a lower specific gravity from that of the first solution so that the second solution is not mixed with the first solution i.e. the PCR reaction mix is overlayed with oil (see page 2 of the instructions, ¶ 2.).

Regarding Claim 3, Perkin Elmer Cetus disclose solution (PCR Reaction Mix) comprising a first solution containing a biopolymer (primer) and a second solution (oil layer) having a lower specific gravity from that of the first solution so that the second solution is not mixed with the first solution and a third solution (Taq polymerase in glycerol) having a higher specific gravity

Art Unit: 1634

that the first solution i.e. the PCR reaction mix is overlayed with oil (see page 2 of the instructions, ¶ 2. and see page 1, Enzyme Characteristics: storage buffer).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Perkin Elmer Cetus (GeneAmp™ DNA Amplification Reagent Kit, 1988) in view of Ness et al (U.S. Patent No. 6,027,890, filed 22 July 1997).

Regarding Claim 4, Perkin Elmer Cetus teach the biochip-producing solutions of Claims 1-3 as described above but they do not teach putting the solution into an inkjet device and injecting the solution to immobilize the biopolymer on a substrate. However, ejecting PCR solutions from inkjet devices onto a substrate to immobilize a biopolymer in the solution was well known in the art at the time the claimed invention was made as taught by Ness et al (Column 74, lines 4-7 and Column 75, lines 19-23). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the inkjet ejection and immobilization of Ness et al to the PCR solution of Perkin Elmer Cetus and to immobilize the PCR products in the solution to thereby eliminate the post-PCR purification as taught by Ness et al (Column 74, lines 4-7) for the obvious benefits of convenience and time-saving elimination of an unnecessary purification step.

Art Unit: 1634

The courts have stated that it would be obvious to omit an element when a function attributed to said element is not desired or required (see Ex parte Wu, 10 USPQ 2031).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
August 13, 2002